

AMENDMENTS TO THE CLAIMS

Applicant presents a full set of claims for the convenience of the Examiner. No amendments of the claims have been made.

1. (Previously Presented) A method for inducing a mucosal immune response, comprising:
administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X1X2CGX3X4 3'

wherein C is unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and
an antigen,

wherein the antigen is not encoded in a nucleic acid vector, the oligonucleotide and the antigen are both administered vaginally, rectally, intranasally, ocularly, or by inhalation to the subject, a cytokine and an immune stimulating complex are not administered to the subject, and the antigen is not a *Streptococcus pneumoniae* antigen.

2-3. (Cancelled)

4. (Previously Presented) The method of claim 1, wherein the antigen is administered concurrently with the oligonucleotide.

5. (Previously Presented) The method of claim 1, wherein the antigen is delivered in conjunction with a colloidal dispersion system.

6. (Original) The method of claim 5, wherein the colloidal dispersion system is selected from the group consisting of macromolecular complexes, nanocapsules, microspheres, beads, and lipid-based systems.

7. (Original) The method of claim 6, wherein the lipid-based system is selected from the group consisting of oil-in-water emulsions, micelles, mixed micelles, and liposomes.

8. (Previously Presented) The method of claim 1, further comprising the step of administering a non-oligonucleotide mucosal adjuvant in conjunction with the antigen.

9. (Previously Presented) The method of claim 8, wherein the non-oligonucleotide mucosal adjuvant is selected from the group consisting of cholera toxin, derivatives of cholera toxin, heat-labile enterotoxin, derivatives of heat-labile enterotoxin, alum, monophosphoryl lipid A (MLP), muramyl dipeptide (MDP), saponins, QS21, cytokines, oil-in-water and other emulsion formulations, squalene-in-water emulsion stabilized with Span 85 and Tween 80 (MF59), syntext adjuvant formulation (SAF), Montanide ISA 720 and oil-in-water emulsion containing stabilizing detergent and micelle-forming agent and poly (PCPP) polymers.

10-11. (Cancelled)

12. (Previously Presented) The method of claim 1, wherein the subject is a subject at risk of developing an infectious disease.

13. (Previously Presented) The method of claim 1, wherein the subject is at risk of developing cancer.

14. (Cancelled)

15. (Original) The method of claim 1, wherein the oligonucleotide includes a phosphate backbone modification which is a phosphorothioate or phosphorodithioate modification.

16. (Original) The method of claim 15, wherein the phosphate backbone modification occurs at the 5' end of the oligonucleotide.

17. (Original) The method of claim 15, wherein the phosphate backbone modification occurs at the 3' end of the oligonucleotide.

18. (Original) The method of claim 1, wherein X1X2 are nucleotides selected from the group consisting of: GpT, GpG, GpA, ApA, ApT, ApG, CpT, CpA, CpG, TpA, TpT, and TpG; and X3X4 are nucleotides selected from the group consisting of: TpT, CpT, ApT, TpG, ApG, CpG, TpC, ApC, CpC, TpA, ApA, and CpA.

19. (Original) The method of claim 1, wherein the oligonucleotide has a sequence including at least the following formula:

5' TCNTX1X2CGX3X4 3'

wherein X1, X2, X3, and X4 are nucleotides, N is a nucleic acid sequence composed of from about 0-25 nucleotides.

20. (Previously Presented) The method of claim 1, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

21. (Cancelled)

22. (Previously Presented) The method of claim 1, wherein the antigen is obtained from an infectious organism selected from the group consisting of infectious bacteria, infectious viruses, infectious parasites, and infectious fungi.

23-24. (Cancelled)

25. (Previously Presented) The method of claim 1, further comprising administering a B-7 costimulatory molecule.

26. (Previously Presented) The method of claim 1, wherein the mucosal immune response is induced in a remote site.

27. (Original) The method of claim 1, further comprising administering a boost of the oligonucleotide.

28. (Original) The method of claim 8, further comprising administering a boost of the oligonucleotide and the non-oligonucleotide mucosal adjuvant.

29-128. (Cancelled)

129. (Previously Presented) The method of claim 1, further comprising identifying a subject in need of a mucosal immune response.

130-134. (Cancelled)

135. (Previously Presented) The method of claim 1, wherein the antigen is a viral antigen.

136. (Previously Presented) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X1X2CGX3X4 3'

wherein C is unmethylated, wherein X1, X2, X3, and X4 are nucleotides, a non-oligonucleotide mucosal adjuvant that is not an immune stimulating complex, and an antigen, wherein the antigen is not encoded in a nucleic acid vector, and wherein the oligonucleotide, the antigen, and the non-oligonucleotide mucosal adjuvant are all administered

rectally, intravaginally, or ocularly, to the subject, and a cytokine is not administered to the subject.

137. (Previously Presented) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X1X2CGX3X4 3'

wherein C is unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and

a viral antigen,

wherein the antigen is not encoded in a nucleic acid vector, the oligonucleotide and the antigen are both administered vaginally, rectally, intranasally, ocularly, or by inhalation to the subject, and a cytokine and an immune stimulating complex are not administered to the subject.

138. (Previously Presented) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X1X2CGX3X4 3'

wherein C is unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and

passively exposing the subject to an antigen,

wherein the antigen is not encoded in a nucleic acid vector, oligonucleotide administration and antigen exposure both occur vaginally, rectally, intranasally, or by inhalation, and a cytokine and an immune stimulating complex are not administered to the subject.

139. (Previously Presented) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X1X2CGX3X4 3'

wherein C is unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and an antigen,

wherein the antigen is not encoded in a nucleic acid vector, the oligonucleotide and the antigen are both administered vaginally, rectally, or ocularly to the subject, and a cytokine and an immune stimulating complex are not administered to the subject.

140. (Previously Presented) The method of claim 139, wherein the antigen is a viral antigen.

141. (Previously Presented) A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X1X2CGX3X4 3'

wherein C is unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and an antigen,

wherein the antigen is not encoded in a nucleic acid vector and is not a *Streptococcus pneumoniae* antigen, the oligonucleotide and the antigen are both administered intranasally or by inhalation to the subject, and a cytokine and an immune stimulating complex are not administered to the subject.

142. (Previously Presented) The method of claim 136, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

143. (Cancelled)

144. (Previously Presented) The method of claim 138, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

145. (Previously Presented) The method of claim 139, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

146. (Previously Presented) The method of claim 141, wherein the antigen is selected from the group consisting of cells, cell extracts, proteins, polypeptides, peptides, polysaccharides, polysaccharide conjugates, peptide mimics of polysaccharides, lipids, glycolipids, carbohydrates, viruses and viral extracts and parasites.

147. (Previously Presented) A method for inducing a mucosal immune response, comprising

mucosally administering to a subject an oligonucleotide 8 to 100 nucleotides in length and comprising 5' X1X2CGX3X4 3' wherein C is unmethylated and X1, X2, X3, and X4 are nucleotides, and an antigen that is not encoded in a nucleic acid vector, and
systemically administering to the subject the antigen.

148. (Previously Presented) The method of claim 147, wherein the oligonucleotide and antigen are administered mucosally as a priming dose, and the antigen is administered systemically as a boost dose.

149. (Previously Presented) The method of claim 147, wherein the antigen is administered systemically as a priming dose, and the oligonucleotide and antigen are administered mucosally as a boost dose.

150. (Previously Presented) The method of claim 147, wherein the antigen is administered systemically with a CpG oligonucleotide 8-100 nucleotides in length and comprising 5' X1X2CGX3X4 3', wherein C is unmethylated, wherein X1, X2, X3, and X4 are nucleotides.

151. (Previously Presented) The method of claim 147, wherein the oligonucleotide and antigen are administered mucosally with a non-nucleic acid mucosal adjuvant.

152. (Previously Presented) The method of claim 147, wherein the antigen is administered systemically with a non-nucleic acid mucosal adjuvant.

153. (Previously Presented) The method of claim 150, wherein the antigen is administered systemically with a non-nucleic acid mucosal adjuvant.

154. (Previously Presented) The method of claim 147, wherein the antigen is a polypeptide or a peptide.

155. (Previously Presented) The method of claim 147, wherein mucosally administering is intranasally administering or administering by inhalation.

156. (Previously Presented) The method of claim 154, wherein mucosally administering is intranasally administering or administering by inhalation.

157. (Previously Presented) The method of claim 147, wherein systemically administering is intramuscularly administering.

158. (Previously Presented) The method of claim 154, wherein systemically administering is intramuscularly administering.

159. (Previously Presented) The method of claim 156, wherein systemically administering is intramuscularly administering.

160. (Currently Amended) A method for inducing an immune response, comprising systemically administering to a subject, as a priming dose, an antigen that is not encoded in a nucleic acid vector, and

mucosally administering to the subject, as a boost dose, an oligonucleotide 8-100 nucleotides in length and comprising 5' X1X2CGX3X4 3' wherein C is unmethylated and X1, X2, X3, and X4 are nucleotides, and the antigen.

161. (Previously Presented) The method of claim 160, wherein the antigen is systemically administered with a CpG oligonucleotide 8-100 nucleotides in length and comprising 5' X1X2CGX3X4 3' wherein C is unmethylated and X1, X2, X3, and X4 are nucleotides.

162. (Previously Presented) The method of claim 160, wherein the antigen is systemically administered with a non-nucleic acid mucosal adjuvant.

163. (Previously Presented) The method of claim 161, wherein the antigen is systemically administered with a non-nucleic acid mucosal adjuvant.

164. (Previously Presented) The method of claim 160, wherein the antigen is mucosally administered to the subject with a non-nucleic acid mucosal adjuvant.

165. (Previously Presented) The method of claim 163, wherein the antigen is mucosally administered to the subject with a non-nucleic acid mucosal adjuvant.

166. (Previously Presented) A method for inducing a mucosal immune response in a subject, comprising

mucosally administering to a subject, as a boost dose, an oligonucleotide 8-100 nucleotides in length and comprising 5' X1X2CGX3X4 3' wherein C is unmethylated and X1, X2, X3, and X4 are nucleotides, and an antigen that is not encoded by a nucleic acid vector, wherein the subject has received a priming dose of antigen administered systemically.